

Public involvement insight report

Shaping the Bone Cap study to improve the mobility for people with leg amputation

Laura Alvarado Cruz and Dylan Ashton. On behalf of the NIHR Imperial Biomedical Research Centre.

Correspondence: publicinvolvement@imperial.ac.uk

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Background

Imperial Biomedical Research Centre

The [Imperial Biomedical Research Centre \(BRC\)](#) is a collaboration between Imperial College London (Imperial) and Imperial College Healthcare NHS Trust, which is funded by a five-year infrastructure grant from the National Institute for Health and Care Research (NIHR) until March 2028. The Imperial BRC supports 14 areas of research focus, including a Biomedical Engineering research theme, as well as a number of core facilities.

The Patient Experience Research Centre

The [Patient Experience Research Centre \(PERC\)](#) is a core facility of the Imperial BRC, which undertakes research on involvement in and engagement with translational research and leads on implementing the Imperial BRC Patient, Public, Involvement, Engagement and Participation (PPIEP) in research Strategy.

Public involvement and engagement in research

The NIHR defines **public involvement** in research as "research being carried out 'with' or 'by' members of the public, rather than 'to', 'about', or 'for' them."

The NIHR defines **public engagement** in research as where information and knowledge about research is provided and disseminated.

Public includes patients, carers, people from underserved communities, and individuals with lived experience of health conditions, whether they are current patients or not.¹

The study

An Imperial researcher, Dr Dylan Ashton, a research associate in orthopaedic implant translation, and Professor Anthony Bull were leading the development of a proposed clinical trial which aims to establish the clinical safety of the BoneCap Implant System and associated implantation procedure in people with transfemoral amputation over 14 months.

Overview and purpose of the study

BoneCap is a fully internal implant that is placed inside the remaining thigh bone (femur). Unlike some bone-anchored prostheses, it does not pass through the skin, meaning the skin remains intact. The implant is initially being developed for people with an above-knee amputation (transfemoral amputation) who experience ongoing mechanical pain, discomfort, or difficulties wearing their prosthesis. BoneCap works by reshaping the end of the thigh bone to create a rounded surface. This aims to make socket use more comfortable, reduce pressure on sensitive areas, and improve the overall experience of using a prosthetic limb.

The research team plans to conduct a 14-month clinical trial to assess the safety of BoneCap. Approximately 10 participants will receive the implant and take part in a series of follow-up assessments throughout the study. These assessments will help the team understand how safe the implant is, how well it works, and what impact it has on participants' comfort, mobility, and quality of life.

Approach and purpose

To ensure the research design reflected what matters most to people with lived experience of lower limb loss, PERC facilitated four online discussion sessions. The first three sessions were attended by different public contributors to accommodate their availability and focused on shaping the proposed study design and involved people with lived

¹ <https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371#definitions-of-involvement-engagement-and-participation>

experience of both below-knee and above-knee amputations. Public contributors provided valuable insights and feedback to help ensure that the study design was relevant, accessible, and aligned with their needs and priorities.

The aims of the first three sessions were as follows:

1. To understand lived experience and unmet needs
2. To explore the acceptability of the BoneCap implant concept
3. To consult people with lived experience on the patient journey and study feasibility

The aims of the fourth discussion session were to:

1. Consult people with lived experience on the proposed public involvement plans for the study.
2. Consult people with lived experience on participant remuneration to ensure that the proposed payment arrangements are inclusive and appropriate.

Sessions overview

The following online discussion sessions were held to discuss the study design:

- **Thursday 16th July 2026** from 1:30pm to 3:00pm via Zoom and attended by two people with lived experience of lower limb loss, and one BLESMA charity representative. In advance of the session, all attendees were provided with a lay summary with an invitation to express interest in the discussion.
- **Thursday 13th August 2026** from 11:00am to 12:30pm via Zoom and attended by three people with lived experience of lower limb loss. In advance of the session, all attendees were provided with a lay summary with an invitation to express interest in the discussion.
- **Thursday 25th August 2026 from 11:00am to 12:30pm** via Zoom and attended by three people with lived experience of lower limb loss. In advance of the session, all attendees were provided with a lay summary with an invitation to express interest in the discussion.
- **Friday 18th September 2026 from 11:00am to 12:30pm** via Microsoft Teams and attended by two people with lived experience of lower limb loss. The session focused on reviewing and discussing the proposed public involvement plans for the clinical trial to ensure that they were meaningful, appropriate, and informed by lived experience. Participant remuneration was also discussed to ensure that appropriate compensation and support provisions were considered and adequately budgeted for, including any reasonable accommodations that participants may require, such as access to psychological support.

Public co-applicant

Following the discussion sessions, one attendee agreed to become a member of the Trial Management Committee and a co-applicant on the funding application. A dedicated meeting was subsequently held to discuss both the role and the research proposal in greater detail. The session with the co-applicant included:

- An overview of the public co-applicant role and its responsibilities.
- A discussion of how feedback from people with lived experience had been incorporated into the study design and funding application.
- A question-and-answer section, including discussion of key issues and suggestions raised by the co-applicant.

Following this meeting, the co-applicant was provided with the research plan and given time to review it in detail and provide comments and questions. A further meeting will be held between Dylan and the co-applicant prior to the submission of the grant application, enabling continued input into and refinement of the proposal. The co-applicant's feedback received to date is summarised in the Feedback and Summary of Actions section of this report.

Attendees

Attendees were recruited through patient networks identified and approached by the project lead, including:

- **Blesma**, a military charity that supports veterans living with limb loss.
- **Finding Your Feet**, a charity that supports individuals and families affected by amputation or limb difference through sporting, and social inclusion initiatives.

Recruitment was conducted through these patient networks using a flyer developed by PERC and the research team (**Appendix B**).

As part of the expression of interest process, attendees were invited to voluntarily provide information about their lived experience to ensure that the discussion sessions were relevant and appropriate to their lived experience.

In line with NIHR payment guidance, attendees received a £41.25 reimbursement for their contribution to each 1.5-hour session, including £5 to cover data costs.

Session feedback

Following the sessions, attendees were sent an online feedback form to comment anonymously on ways the sessions could be improved and to give any additional views on the topics covered in the session. Comments received relating to the questions posed in the discussion session were integrated into the 'Feedback and summary of actions' section of this report. Attendees were also given the opportunity to sign up for future public involvement, engagement, and participation opportunities. General feedback on the session is summarised at **Appendix C**.

The questions asked by attendees during the sessions, are summarised at **Appendix A**.

Feedback and summary of actions

The following responses to public contributors' feedback were provided by the research team in relation to the comments made during the public involvement sessions on the study design and public involvement plans.

Topics/issues raised and discussed	Response to public contributors' feedback
Study design	
Patient priorities and insights on BoneCap Overall, attendees' impressions of BoneCap were positive, with several describing it as an "interesting" concept. Public contributors identified a range of priorities and considerations based on their individual experiences of limb loss and prosthetic use: • Safety was the most frequently discussed priority. Attendees emphasised that BoneCap would need to demonstrate a strong safety profile, particularly regarding surgical risks and the potential for implant-related infection. • One contributor highlighted the importance of ensuring that BoneCap does not limit existing mobility or restrict participation in activities currently possible with their prosthetic socket. • One contributor identified recovery and rehabilitation times following BoneCap implantation as a key factor influencing acceptability. • One contributor noted that the concept appeared to be focused primarily on above-knee amputees and suggested that its potential application for below-knee and through-knee amputees should also be explored. • Some contributors highlighted concern regarding potential changes in bone growth and bone volume around the implant. They were particularly interested in whether BoneCap could preserve or improve functional limb length, minimise any negative impact on prosthetic fitting, and avoid creating a need for additional clinical appointments. • Questions were raised about how BoneCap would be integrated into existing NHS services and whether current care pathways could support implementation of the technology. • Contributors also highlighted the importance of understanding how BoneCap compares with existing options, particularly osseointegration,	The research team acknowledged that the proposed study is a first-in-human clinical trial, with a primary focus on assessing the safety and feasibility of BoneCap. Establishing a clear safety profile, including monitoring for adverse events and complications, will therefore be a key outcome of the trial. The team recognised that infection risk and surgical complications were important concerns for participants. Based on current knowledge, BoneCap is not expected to carry a greater risk of infection or surgical complications than comparable orthopaedic implant procedures. However, these risks will be carefully monitored and evaluated throughout the study. The team also acknowledged the importance of understanding how BoneCap compares with existing treatment options, particularly osseointegration. Actions arising from their feedback In response to the discussion, the research team will: • Co-design participant-facing study materials with people with lived experience of limb loss to ensure that information is clear, accessible, and relevant. • Ensure study materials clearly explain the potential risks and benefits of BoneCap, including surgical risks, infection risk, and possible revision procedures. • Provide clear information on how BoneCap differs from existing treatment options, including osseointegration, and the potential advantages and limitations of each approach. • Retain safety as the primary outcome of the first-in-human trial, reflecting its importance to both participants and the research team.

Topics/issues raised and discussed	Response to public contributors' feedback
in terms of mobility, comfort, rehabilitation requirements, and long-term outcomes. One suggested that BoneCap might be particularly beneficial for those with initial amputation surgery or as part of stump revision procedures where current outcomes are poor.	- Evaluate outcomes that are important to patients, including mobility, rehabilitation, preservation of functional limb length, comfort, independence, and the impact of BoneCap on prosthetic fitting. - Explore how BoneCap could be integrated into NHS services, including the clinical pathways, multidisciplinary support, and follow-up arrangements required to support successful implementation if patient outcomes are positive.
Patient outcomes Attendees shared their views on the improvements they would most like to see resulting from this research and identified the outcomes that were most important to them. These included: - Increased weight-bearing ability. - Reduced pain. - Improved mobility, enabling individuals to carry out day-to-day activities more easily. - Improved functional outcomes in the short to medium term. - Enhanced mobility for individuals with high-level above-knee amputations. - Safety, with a particular emphasis on minimising the risk of infection. - Increased confidence in using their prosthesis. - A reduction in the need for frequent prosthetic replacements or adjustments. Attendees were generally positive about the outcomes proposed by the research team. They also suggested several additional outcomes that should be considered: - Mental health and psychological wellbeing. Attendees also recommended that mental health support should be available to participants throughout the trial.	Actions arising from their feedback In response to the discussion, the research team will: - Ensure that the outcomes identified as important by public contributors are included in the trial outcome framework and measured as part of the study. - Include funding within the study proposal for psychological support, should participants require it during the trial. - As many of the suggested outcomes are already captured within the proposed study, place additional emphasis on monitoring prosthesis changes or replacements throughout the follow-up period. - Include measures of participants' confidence in using their prosthesis to better understand the impact of the intervention on daily life and independence. - Consider how the findings from these patient-prioritised outcomes can inform future improvements in clinical care and rehabilitation pathways.

Topics/issues raised and discussed	Response to public contributors' feedback
Inclusion and exclusion criteria for the proposed trial: Overall, attendees mentioned that the proposed inclusion and exclusion criteria were appropriate for an initial clinical trial. - Contributors asked clarification of specific terms used within the eligibility criteria, highlighting the importance of presenting this information in plain, accessible language. Examples included immunosuppression, psychiatric or cognitive impairment, and abnormal bone growth. - One participant emphasised the importance of assessing bone quality during the screening process and asked how this would be evaluated. - Some participants noted that certain exclusion criteria could represent barriers to participation, particularly poor bone quality, significant bone defects, and diabetes-related complications. The research team clarified that concerns related primarily to severe or poorly controlled diabetes, and that individuals with well-managed diabetes would still be eligible for participation. - Similarly, one contributor highlighted the importance of considering whether individuals with vascular-related amputations could be included in the study and requested further clarification on eligibility for this group. - One contributor noted the absence of an upper age limit within the exclusion criteria and supported maintaining broad eligibility criteria while allowing clinical judgement to guide individual participant suitability. - One contributor suggested that participants with osteopenia or early-stage osteoporosis may require additional assessment and monitoring.	Actions arising from their feedback In response to the discussion, the research team will: - Co-design participant-facing study materials with people with lived experience of limb loss to ensure that information about the inclusion and exclusion criteria is clear, and accessible. - Ensure that bone quality is assessed as part of the screening process and explore appropriate monitoring or additional risk assessment for participants with osteopenia or early-stage osteoporosis. - Clearly communicate how diabetes-related eligibility criteria will be applied. The team confirmed that individuals with well-controlled diabetes may be eligible to participate, while those with uncontrolled diabetes may be excluded for safety reasons. - Review the eligibility criteria and accompanying participant information to ensure that key terms, such as immunosuppression, psychiatric or cognitive impairment, and abnormal bone growth, are clearly explained.
Proposed recruitment strategy: Attendees provided recommendations to support the development of the recruitment strategy: - Attendees viewed the recruitment of patients through clinicians as a positive approach. - As additional avenues for reaching patients with lived experience, it was suggested that wheelchair and rehabilitation services could be engaged to help raise awareness of the project. - It was highlighted that individuals experiencing difficulties with their prosthesis may no longer be in regular contact with prosthetic or rehabilitation services. Therefore, attendees recommended prioritising patient networks, charities, and community organisations as key recruitment channels. Organisations specifically mentioned included BLESMA and Steel Bones.	Actions arising from their feedback In response to the discussion, the research team will: Emphasise building relationships with charities, patient networks, and community groups as a key element of the recruitment strategy. Recruitment will also be supported through clinical networks and NHS services, such as rehabilitation and wheelchair services.

Topics/issues raised and discussed	Response to public contributors' feedback
Participants' study journey: Overall, attendees were positive about the proposed participant study journey and considered the schedule of study visits and follow-up assessments appropriate. They also provided the following recommendations for the study team: • While the timing of study visits and the long-term follow-up period were considered appropriate, allowing sufficient time for healing, adaptation, and outcome assessment, attendees recommended maintaining regular contact with participants during longer intervals between follow-up visits to address any issues or concerns that may arise. • Where appropriate, allow some appointments to take place at local limb centres to reduce the burden of travel. • Ensure effective communication and coordination between participants' local NHS teams and the trial team throughout the study. • Provide practical support following surgery, including medical transport, accessible taxis, and assistance with travel and logistical arrangements. • Consider the additional support needs of participants who may need to travel alone. • Reimburse travel and accommodation costs, particularly for participants travelling long distances to attend study visits. If possible, also covering childcare costs. • Provide compensation for participants' time and contribution to the trial. • Consider providing access to physiotherapy support following surgery to aid recovery and rehabilitation. • Combine appointments wherever possible to minimise travel requirements and reduce participant burden. • Enable participants to prepare well in advance for surgery, including discussions with employers, arranging childcare, and managing family or caring responsibilities. This may help reduce anxiety and support informed decision-making. • Consider increasing the number of trial sites or locations to minimise travel burden and improve accessibility for participants. • Clear, consistent, and balanced communication from clinicians was considered essential to support participants throughout the decision-making process.	Actions arising from their feedback In response to the discussion, the research team will: • Reimburse participants for all reasonable travel and accommodation expenses incurred as part of the study. • Provide compensation for participants' time spent attending study visits and follow-up appointments. • Cover childcare costs, where required, to reduce barriers to participation throughout the study and follow-up period. • Provide practical support to help participants prepare for surgery, including planning for work, family, and caring responsibilities. • Emphasise to the clinical team the importance of providing clear, consistent, and balanced communication, and ensure participants are aware of all available sources of support. • Provide participants with a named point of contact (Dylan Ashton) who is available for ongoing communication and support, particularly during longer intervals between follow-up visits. • Explore pathways that would enable participants to access support through their local limb centres and establish effective communication and coordination between the trial team and participants' local NHS care teams throughout the study. • Explore connections with clinicals who have performed similar procedures to BoneCap.

Topics/issues raised and discussed	Response to public contributors' feedback
Attendees also identified potential challenges that may affect recruitment and participation in the study: • People whose current prosthetic solution is functioning well may be reluctant to undergo additional surgery. • Some people may feel uncomfortable with the idea of receiving an internal implant. However, attendees noted that this concern would not necessarily influence their own decision-making. • As this would be an elective rather than an urgent procedure, potential participants are likely to spend considerable time weighing the risks and benefits before deciding whether to take part. • Attendees discussed the emotional burden associated with multiple healthcare appointments, particularly for those experiencing mobility difficulties or delays in accessing clinical support. • Consider whether participants can continue using their existing prosthetic sockets, where appropriate, as socket modifications may affect comfort, and confidence in using their prosthesis.	The study team will consider the participation challenges highlighted during the discussion. • These will be explored further with public partners on the Trial Management and Steering Committee and members of the Patient Advisory Group at the start of the trial. • This collaborative approach will help co-design the recruitment strategy and refine the proposed participant journey, ensuring that the study protocol is patient-centred and reflects the needs and priorities of potential participants.
Further considerations on participants' remuneration: Attendees identified additional provisions that should be incorporated into the participant journey: • Provision of refreshments during participant follow-up visits. • Reimbursement of transport via private car hire instead of public transport. • Offer study participants access to hospital transport services for follow-up visits, where available and appropriate. • Reimbursement of travel expenses associated with follow-up appointments with a physiotherapist. Attendees also considered that: • Accommodation costs for both the study participant and, where required, an accompanying person should be covered to ensure accessibility. • Compensation for time spent attending follow-up visits (£200 per visit) was acceptable and appropriate. • The costs currently included within the proposal were appropriate and reflected the anticipated needs of participants.	Actions arising from their feedback In response to the discussion, the research team will: • Include funding within the study budget for refreshments during participant study visits. • Amend the travel reimbursement budget to prioritise the use of private car hire where appropriate, as these were identified as more accessible and preferable modes of transport for participants with lived experience of lower limb loss. • Include reimbursement for travel expenses associated with physiotherapy follow up appointments. • The study team will explore hospital transport services availability where appropriate.

Topics/issues raised and discussed	Response to public contributors' feedback
Public involvement plans: Attendees considered the proposed public involvement plans to be appropriate and highlighted the importance of: • Providing flexibility in meeting arrangements for public contributors, including scheduling meetings at times that are suitable for them, such as evenings where appropriate. • Establishing clear ways of working with public contributors throughout the trial, including mechanisms for keeping contributors informed if they are unable to attend meetings. This could include updates via email or collaborative platforms such as Slack. Attendees also considered the proposed governance structure to be appropriate. However, they suggested that: • Public contributors serving on governance committees should have a mechanism for obtaining feedback from study participants throughout the project, enabling them to better understand participants' experiences, needs, and support requirements. • Contributors noted that individuals with shared lived experience may be particularly well placed to engage with participants and gather meaningful feedback, as they can often relate to and understand participants' perspectives more effectively.	Actions arising from their feedback In response to the discussion, the research team will: • Co-design ways of working with public contributors at the outset of the trial, ensuring that all contributors are able to participate in a manner that is appropriate, accessible, and meaningful to them. • Ensure that the public co-applicant is a member of the Trial Management Committee and, through this role, contributes to oversight of the study. In addition, an independent public contributor will be appointed to the Trial Steering Committee to provide broader public representation. • Develop and co-design a mechanism for gathering and communicating participants' experiences, feedback, and support needs throughout the trial. This process will be developed collaboratively by the research team (including the public co-applicant), and the Patient Advisory Group, ensuring that participant confidentiality is maintained while enabling public contributors to understand emerging support requirements and provide meaningful input to the research team. • Explore opportunities for study participants to connect with one another during the trial, should participants wish to do so. Public contributors highlighted that peer connection may provide valuable mutual support and enhance participants' overall experience of taking part in the study.

Appendices

Appendix A: Questions asked during the sessions

- How would BoneCap be integrated into existing NHS services and care pathways?
- What would be the recovery and rehabilitation time after the surgery?
- If BoneCap is successful, where would it be available?
- What is BoneCap's infections risk?
- Would closer collaboration between physiotherapy, prosthetic, and surgical teams be required to support the implementation of BoneCap, particularly given that some NHS services may be risk-averse?
- Would BoneCap provide additional limb length for individuals with limited muscle and bone tissue in their residual limb?
- How would BoneCap compare with current suspension systems, such as the Linard suspension system, in terms of stability and function?
- What are the advantages and disadvantages of BoneCap compared with osseointegration, particularly regarding mobility, limb length, and overall outcomes?
- How would infections associated with BoneCap be managed?
- How does BoneCap function biomechanically? Does the implant design allow for direct muscle attachment to the implant?
- What would happen if the implant did not work as intended?
- If necessary, could the implant be removed safely, and what would the implications of removal be for the participant?
- How bone quality will be assessed during the study?
- Would people with vascular related amputations be eligible to take part in the study?
- If a participant has a complication, do they have to travel to London for treatment?
- Would participants be reimbursed for their time and expenses?
- What physiotherapy support will the participants receive after the surgery?

Appendix B: Public involvement session flyer used for dissemination in clinics

Would you like to give your views on a project aiming to improve pain, comfort and mobility for people with leg amputation?



Background of the project

The researchers from Imperial College London are applying for NIHR funding to develop a new implant designed to address pain and discomfort caused by current prosthetic sockets.

The implant sits entirely within the body and reshapes the end of the bone so that pressure can be distributed more evenly within a standard prosthetic socket. Its aim is to reduce pain, improve comfort, and restore the ability to bear weight through the bone during everyday use of a prosthesis, without breaking the skin or increasing the risk of infection.

What's involved in this opportunity?



A 1 to 1.5 hours online meeting on a date and a time based on your availability to share your views on the project, including ways to make it more relevant and beneficial to patients.



You will be given an introduction explaining the research proposal followed by an opportunity to ask questions.



You will be remunerated at £27.5/hour for actively participating in the meeting plus a £5 contribution towards data expenses. Payment will be made directly to your personal UK bank account.

Who can apply?

Anyone aged 18 or over who:

- has lived experience of lower limb amputation (above or below knee) due to trauma, vascular-related diseases, or cancer.
- Currently uses a prosthesis, or has experience of trying to use one.

How do I express my interest?

Sign-up via the link below or scan the QR Code:

https://imperial.eu.qualtrics.com/jfe/form/SV_8HTjnNjdZAOpbGC

Alternatively, email us at publicinvolvement@imperial.ac.uk or call us at: 020 7594 3464

Contact us:  publicinvolvement@imperial.ac.uk



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Appendix C: Responses to feedback form questions

3/8 attendees from the first three sessions completed the online feedback form and their complete responses are set out below

Q1. On a scale of 1-5, how would you rate the session?					
No response	Very poor	Poor	Fair	Good	Very good
0	0	0	0	2	1
Q2. Please tell us why you chose the above rating:					
• Because it was good • Informative. Supportive. Interesting. Relevant. • It was very informative and I got a good understanding of what the bone cap worked and how it helped above knee amputees.					
Q3. Please let us know what went well:					
• All • Quality of presentation and information. Facilitation to offer own lived experience and thoughts • The session was efficient and think that all participants brought value based on their experiences.					
Q4. Please let us know what could have made this even better:					
• Nothing • N/A • It would be better to get a better understanding of how it can help below knee amputees. However, I do understand that it is not yet being trialled on them.					
Q5. Do you think you were provided with sufficient information about the session prior to attending?					
Yes					
3					
Q6. Did you find the presentation easy to understand?					
Yes					
3					

Q7. How informative did you find this session?					
No response	Not at all	Slightly	Moderately	Very	Extremely
0	0	0	0	2	1
Q8. How likely are you to attend a session like this again?					

No response	Not at all	Slightly	Moderately	Very	Extremely
0	0	0	1	1	1

Q9. What opportunities or potential challenges should we consider before moving into clinical study?

- Getting our limb centres involved
- Opportunity to connect with similar procedures previously performed
- The ease for participants that aren't close to London and if they can recover using the same clinic as they get their current prosthetics made at

Q10. Regarding the proposed study visits (6 full day visits over 14 months) and assessments, what parts of the study journey feel achievable? Or challenging?

- Achievable with practical support
- All of it seems achievable but similar challenges to the ones mentioned in the previous questions.

Q11. Are we measuring outcomes that matter most to patients and clinical practice? Please let us know your top priorities and any other suggestions below:

- Prosthetic socket fit and comfort
- Impact on mobility (distance walked) by strengthening and possibly marginally lengthening residual limb
- I think mental health needs to be prioritised in this as psychologically, it can be triggering for an amputee to go through the recovery process again

Q12. What would matter most to you in improving the experience for future patients taking part in a Bone Cap study?

- Impact evidence
- Evidence of infection
- Understanding the full risks. i.e. the infection rate, recovery times and if it can be reversed if needed.